



IFW

Practitioner's Docket No. 701039-054340

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Real Lemieux and Josee Lamoureux

Application No.: 10/643,743

Group No.: To be assigned

Filed: August 19, 2003

Examiner: To be assigned

For: PURIFICATION OF POLYREACTIVE AUTOANTIBODIES AND USES THEREOF

CERTIFICATE OF MAILING

I hereby certify that this correspondence, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner of Patents, Box 1450, Alexandria, VA 22313-1450 .

Date:

12/16/04

Debra J. Kellom
Debra J. Kellom

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir/Madam:

INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §1.56, 1.97, and 1.98, Applicants wish to bring to the Examiner's attention the following references, References A1-A2, B1 and C1-C26 cited in the attached Forms PTO/SB/08a and b.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

X

(1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or

—

(2) within three months of the mailing date of the PCT International Search Report; or

- _____ (3) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- _____ (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

It is respectfully requested that each of the documents shown on the attached form(s) PTO/SB/08a be made of record in this application.

Copies of these documents (CHECK ONE):

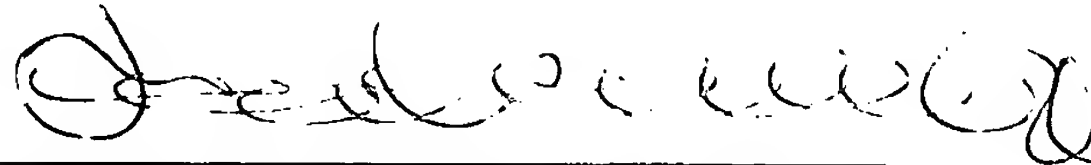
- X are enclosed herewith that have not been previously submitted; or
- _____ have been cited in the parent application, and are thus not being resubmitted herein.

FEE AUTHORIZATION

The Commissioner is authorized to charge fee deficiencies or credit overpayments associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Date: December 16, 2004

Respectfully submitted,



David S. Resnick (Reg. No. 34,235)
Leena H. Karttunen (37 C.F.R. §10.9(b))
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110-2131
(617) 345-6057

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/643,743		
		Filing Date	August 19, 2003		
		First Named Inventor	Réal Lemieux et al.		
		Art Unit	1645		
		Examiner Name	Not yet known		
Sheet	2	of	4	Attorney Docket Number	701826-054340

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	C1	Adib M, Ragimbeau J, Avrameas S, Ternynck T. IgG autoantibody activity in normal mouse serum is controlled by IgM. J Immunol. 1990;145:3807-3813	
	C2	Avrameas S, Ternynck T. The natural autoantibodies system: between hypotheses and facts. Mol Immunol. 1993;30:1133-1142	
	C3	Ballow M. Intravenous immunoglobulins: clinical experience and viral safety. J Am Pharm Assoc. 2002;42:449-459	
	C4	Berneman A, Guilbert B, Eschrich S, Avrameas S. IgG auto- and polyreactivities of normal human sera. Mol Immunol. 1993;30:1499-1510	
	C5	Dahl MV, Bridges AG. Intravenous immune globulin: fighting antibodies with antibodies. J Am Acad Dermatol. 2001;45:775-783	
	C6	Dietrich G, Algiman M, Y S, Nydegger UE, Kazatchkine MD. Origin of anti-idiotypic activity against anti-factor VIII autoantibodies in pools of normal human immunoglobulin G (IVIg). Blood. 1992;79:2946-2951	
	C7	Emmenegger U, Frey U, Reimers A, Fux C, Semela D, Cottagnoud P, Spaeth PJ, Neftel KA. Hyperferritinemia as indicator for intravenous immunoglobulin treatment in reactive macrophage activation syndromes. AmJ Hematol. 2001;68:4-10	
	C8	Fehr J, Hofmann V, Kappeler U. Transient reversal of thrombocytopenia in idiopathic thrombocytopenia purpura by high-dose intravenous gamma globulin. N Eng J Med. 1982;306:1254-1258	
	C9	Hadley AG, Kumpel BM, Merry AH. The chemiluminescent response of human monocytes to red cells sensitized with monoclonal anti-Rh(D) antibodies. Clin Lab Haematol. 1988;10:377-384	
	C10	Kazatchkine MD, Kaveri SV. Immunomodulation of autoimmune and inflammatory diseases with intravenous immune globulin. N Eng J Med. 2001;345:747-755	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/643,743
				Filing Date	August 19, 2003
				First Named Inventor	Réal Lemieux et al.
				Art Unit	1645
				Examiner Name	Not yet known
Sheet	3	of	4	Attorney Docket Number	701826--054340

	C11	Kessary-Shoham H, Levy Y, Shoenfeld Y, Lorber M, Gershon H. In vivo administration of intravenous immunoglobulin (IVig) can lead to enhanced erythrocyte sequestration. J Autoimmun. 1999;13:129-135	
	C12	Kimberly RP, Salmon JE, Bussel JB, Crow MK, Hilgartner MW. Modulation of mononuclear phagocyte function by intravenous immunoglobulin. J Immunol. 1984;132:745-750	
	C13	Lacroix-Desmazes S, Kaveri SV, Mouthon L, Ayoub A, Evelyne M, Coutinho A, Kazatchkine MD. Self-reactive antibodies (natural autoantibodies) in healthy individuals. J Immunol Methods. 1998;216:117-137	
	C14	Larroche C, Chanseaud Y, Garcia de la Pena-Lefebvre P, Mouthon L. Mechanisms of intravenous immunoglobulin action in the treatment of autoimmune disorders. Biodrugs. 2002;16:47-55	
	C15	Lazarus AH, Freedman J, Semple JW. Intravenous immunoglobulin and anti-D in idiopathic thrombocytopenia purpura (ITP): mechanisms of action. Transfus Sci. 1998;19:289-294	
	C16	Lock RJ, Unsworth DJ. Measurement of immune complexes is not useful in routine clinical practice. Ann Clin Biochem. 2000;37:253-261	
	C17	Louzir H, Ternynck T, Gorgi Y, Ayed K, Avrameas S. Enzyme immunoassay analysis of antibody specificities present in the circulating immune complexes of selected pathological sera. J Immunol Methods. 1988;114:145-153	
	C18	Matejtschuk P, Chidwick K, Prince A, More JE, Goldblatt E. A direct comparison of the antigen-specific antibody profiles of intravenous immunoglobulins derived from US and UK donors plasmas. Vox Sang. 2002;83:17-22	
	C19	Mizutani H, Engelman RW, Kurata Y, Ikehara S, Good RA. Development and characterization of monoclonal antiplatelet autoantibodies from autoimmune thrombocytopenia purpura-prone (NZW x BXSB) F1 mice. Blood. 1993;82:837-844	
	C20	Ohlson S, Zetterstrand K. Detection of circulating immune complexes by PEG precipitation combined with ELISA. J Immunol Methods. 1985;77:87-93	
	C21	Rossi F, Guilbert B, Tonnelle C, Ternynck T, Fumoux F, Avrameas S, Kazatchkine MD. Idiotypic interactions between normal human polyspecific IgG and natural IgM antibodies. Eur J Immunol. 1990;20:2089-2094	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/643,743		
		Filing Date	August 19, 2003		
		First Named Inventor	Réal Lemieux et al.		
		Art Unit	1645		
		Examiner Name	Not yet known		
Sheet	4	of	4	Attorney Docket Number	701826--054340

	C22	Samuelsson A, Towers TL, Ravetch JV. Anti-inflammatory activity of IVIg mediated through the inhibitory Fc receptor. Science. 2001;291:484-486	
	C23	Theofilopoulos AN. The Raji, conglutinin, and anti-C3 assays for the detection of complement-fixing immune complexes. Methods Enzymol. 1981;74:511-530	
	C24	Vassilev TL, Bineva IL, Dietrich G, Kaveri SV, Kazatchkine MD. Variable region-connected, dimeric fraction of intravenous immunoglobulin enriched in natural autoantibodies. J Autoimmun. 1995;8:405-413	
	C25	Vassilev TL et al., "Inhibition of cell adhesion by antibodies to Arg-Gly-Asp(RGD) in normal immunoglobulin for therapeutic use...". BLOOD, W. B. SAUNDERS COMPAGNY vol.93, no. 11, 1999, pages 3624-3631	
	C26	Kaveri Srini et al: "Antibodies to a conserved region of HLA class I molecules, capable of modulating CD8 T cell-mediated function, are present in...": Journal of Clinical Investigation, vol. 97,, no.3, 1996, pages 865-869.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.